AUG 0 1 2002

K022162

stryker INSTRUMENTS

4100 East Milham Avenue
Kalamazoo, MI 49001
Phone (616) 323-7700
(800) 253-3210

510(k) Summary

Trade Name:	Stryker T4 Urethane Zippered Toga, Stryker T4 Urethane Pullover Toga, Stryker T4 Urethane Hood
Common Name:	Surgical gown and hood
Classification Name:	Surgical Apparel (per 21 CFR section 878.4040)
Equivalent to:	Stryker Steri-shield Personal Protection System (K944393, K993148, K011755)
Device Description:	The Stryker Personal Protection Systems include a self-contained ventilation helmet, a hood, a toga, rechargeable battery, and accessories.
Intended Use:	The Stryker T4 Urethane Hood, Zippered Toga, and Pullover Toga are components of a personal protection system that is intended to provide a barrier between the operating environment and the members of the surgical team in order to help protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.
Technological Comparison:	Technological characteristics are the same as previously cleared for the Stryker Steri-sheild Personal Protection System (K944393, K993148, K011755).
Submitted by:	Dannielle C. Wheeler Regulatory Affairs Representative Stryker Instruments
Date Submitted:	July 2, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 01 2002

Ms. Dannielle Wheeler
Regulatory Affairs Representative
Stryker Instruments
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K022162
Trade/Device Name: Stryker T4 Urethane Hood, Stryker T4 Urethane Zipper Toga, and Pullover Toga
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA, LYU and FXY
Dated: July 2, 2002
Received: July 3, 2002

Dear Ms. Wheeler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K022162

Device Name The Stryker T4 Personal Protection System: Stryker T4 Urethane Hood, Zippered Toga, and Pullover Toga

Indications The Stryker T4 Urethane Hood, Zippered Toga, and Pullover Toga are components of a personal protection system that is intended to provide a barrier between the operating environment and the members of the surgical team in order to help protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K022162